K110225 page 1

MAY 13 2011

510(k) Summary of Safety and Effectiveness for the VenaCure 1470 Laser:

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

Submitter:	AngioDynamics, Inc. 14 Plaza Drive Latham, NY 12110
Contact Person:	Teri Juckett 14 Plaza Drive Latham, NY 12110 Phone: 518-795-1142 Fax: 518-795-1402
Summary Preparation Date:	January 11, 2011

2. Names

Device Name:	AngioDynamics, Inc. VenaCure 1470 Laser
Classification Name:	Class II Laser Instrument, Surgical Powered Product Code: GEX

3. Predicate Devices

The AngioDynamics VenaCure 1470 Laser is substantially equivalent to the AngioDynamics Delta 15 and AngioDynamics Delta 30 Lasers, K051995, and the Biolitec 15W Ceralas D 1470nm Diode Laser, K082225.

4. Device Description

The purpose of this Traditional 510(k) is to notify FDA of the proposed new AngioDynamics VenaCure 1470 Laser, which is equivalent to the AngioDynamics Delta 15 and AngioDynamics Delta 30 Lasers.

The AngioDynamics VenaCure 1470 Laser is a Class IV Diode Laser with a wavelength of 1470nm. The predicate Biolitec Laser has the same 1470nm wavelength.

The 1470 Laser is intended for use in delivering up to 12 Watts of energy and is intended to be used with AngioDynamics Fiber Optic Delivery System Procedure Kits for use in endovascular coagulation of the Great Saphenous Vein in patients with superficial vein reflux, for the treatment of varicose veins and varicosities associated with superficial reflux of the Great Saphenous Vein, and for the treatment of incompetence and reflux of superficial veins of the lower extremity.

5. Indications for Use

The AngioDynamics VenaCure 1470 Laser is intended for use in the treatment of varicose veins and varicosities with superficial reflux of the Greater Saphenous Vein, and in the treatment of incompetent refluxing veins in the superficial venous system in the lower limb.

6. Performance Data

The AngioDynamics VenaCure 1470 Laser has undergone a comprehensive series of test protocols, listed below, in order to qualify and validate the performance of the devices. The results of the qualification/validation demonstrates equivalent performance to the predicate devices which themselves have substantial clinical and market evidence of acceptable performance. The AngioDynamics VenaCure 1470 Laser is therefore validated for use on this basis.

EMC Testing
Software Verification / Validation
Product Life Time & Life Cycle Testing
Electrical Safety Testing
Laser Safety Testing
Environmental Testing
Optical Output Performance
Output Power Stability
System Performance
Product Shock and Vibration
Transit Testing

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AngioDynamics, Inc.
% Ms. Teri Juckett
14 Plaza Drive
Latham, New York 12110

MAY 13 2011

Re: K110225
Trade/Device Name: AngioDynamics, Inc. VenaCure 1470 Laser and Accessories
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general surgery and in plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: April 07, 2011
Received: April 11, 2011

Dear Ms. Juckett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Application: Traditional 510(k): Device Modification K110225

Device Name: AngioDynamics, VenaCure 1470 Laser

Indications for Use:

The AngioDynamics, VenaCure 1470 Laser is indicated for use in the treatment of varicose veins and varicosities with superficial reflux of the Greater Saphenous Vein, and in the treatment of incompetent refluxing veins in the superficial venous system in the lower limb.

Prescription Use ____X____ **OR** **Over-the-Counter Use**

(Per 21 CFR 801.109)

Please do not write below this line - continue on another page if needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark R. Ogden for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110225